

**REMARKS**

Reconsideration and withdrawal of the Restriction Requirement and Election of Species Requirement are respectfully requested in view of the remarks herewith.

**I. RESPONSE TO RESTRICTION REQUIREMENT**

The September 4, 2002 Office Action required restriction from among the following Groups under 35 U.S.C. §121:

- Group I: Claims 1-43, drawn to a device for increasing the relative number of undifferentiated cells in a cell population, classified in class 435, subclass 284.1; and
- Group II: Claims 44-97, drawn to a method for preparing an undifferentiated cell comprising retro differentiating a more committed cell to a less committed cell, classified in class 435, subclass 377.

Applicants respectfully elect Group I, with traverse.

The Office Action alleges that the claims of Group I and Group II constitute distinct inventions because they are related as process and apparatus for its practice. Under MPEP § 806.05 (e) inventions related as process and apparatus for its practice are distinct if it can be shown that either (1) the process as claimed can be practiced by another materially different process or by hand, or (2) the apparatus as claimed can be used to practice another materially different process. The Office Action asserts that in this case the apparatus of Group I can be used for the materially different process of preparing a transformed cell line. Further, the Restriction Requirement maintains that "[b]ecause these inventions are distinct ...and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper."

It is respectfully requested that the Restriction Requirement be reconsidered and withdrawn, and Groups I and II be rejoined such that claims 1-97 are searched and examined together.

The Office Action asserted that the apparatus of Group I can be used to practice the materially different process of preparing a transformed cell line. However, it is respectfully submitted that the preparation of a transformed cell line is not a materially different process, and that, in fact, the use of the apparatus to prepare a transformed cell line falls within the scope of

Group I as claimed. Group I relates to a device for increasing the relative number of undifferentiated cells in a population. It is hereby submitted that undifferentiated cells may comprise transformed cells. The process of transformation in relation to animal cells refers to "the acquisition of cancer like properties" following treatment with an agent (Alberts et al., Molecular Biology of the Cell. Third Edition, 1994). One of the defining features of cancer cells is their ability to proliferate at a higher rate than their neighbors thus giving rise to a tumor. Alberts et al., states that "if a transformed cell is to generate a steadily growing clone of progeny ....the process of differentiation must be deranged so that .....cells retain an ability to carry on dividing indefinitely;" i.e. if a differentiated slowly proliferating or non-proliferating cell is to be transformed, there must be some dedifferentiation to a more primitive proliferative state. Thus, many transformed cells are also undifferentiated cells. In light of the above, it is respectfully submitted that the use of the apparatus of Group I to prepare a transformed cell line does not constitute a materially different process to the claimed use of the apparatus, and thus, the assertion that Group I and Group II are distinct is not proper.

In further traverse, it is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct (MPEP § 803). Second, searching the additional inventions must constitute an undue burden on the examiner if restriction is not required. Under Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP § 803) (emphasis added).

The present invention relates to, *inter alia*, methods of preparing undifferentiated cells by retro differentiating more committed cells into less committed cells. It is respectfully asserted that the Office Action, in defining the subject matter of Group I, fails to recognize that the device provides a method of increasing the relative number of cells in a population by retro-differentiating more committed cells into less committed cells. Thus, a search of the claims of Group I would consequently and inextricably encompass a search of the claims included in Group II and vice versa. For example, claims 19-22 in Group I and claims 44-49 in Group II are directed to sources of committed cells, claim 39 in Group I and claim 43 in Group II are directed to use of buffy coat blood samples, claims 23-26 in Group I and claims 50-53 in Group II are directed to types of undifferentiated cells produced by retro differentiation of committed cells,

claims 28-32 in Group I and claims 55-59 in Group II are directed to receptors that mediate capture, recognition or presentation of antigens at the surface of the committed cells, and claims 33-38 in Group I and claims 60-64 in Group 2 are directed to retro differentiation agents. Thus, examination of either Group I or Group II mandates consideration of the patentable elements in the other Group. Indeed, the search and examination of each Group is likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner.

Thus, Restriction has not been shown to be proper, especially since the requisite showing of serious burden has not been made in the Office Action. All of the preceding, therefore, mitigate against restriction. Accordingly, it is respectfully requested that the restriction requirement be reconsidered and withdrawn.

## **II. RESPONSE TO ELECTION REQUIREMENT**

The September 4, 2002 Office Action further required an election of species at page 3. Hematopoietic cells from Group A, CD34<sup>+</sup> cell surface marker from Group B, and CFC-T cells and T-cells from Group C, are hereby elected, with traverse. It is understood that the election of species is only for search and examination purposes, and that it can be expanded to ultimately encompass generic claims such as claim 1 upon determination of allowable subject matter. As will be shown below, species (i) and (ii) of Group C should be rejoined, such that Applicants elect CFC T-cells and T-cells, and CFC B-cells and B-cells.

The Office Action alleges that the application contains claims directed to patentably distinct species of the claimed invention and therefore requires an election of species. However, the requirement of species election is requested without appropriate or due reason. The Examiner states that "Applicant is required under 35 U.S.C. 121 to elect a single disclosed species..." but fails to provide support as to the reason why the members of each species are patentably distinct.

In further traverse, a claim reciting all species of Group C has previously been deemed allowable subject matter, as evidenced by claim 16 of U.S. Patent No. 6,090,625.

Further, as the species are not too many in number, it is respectfully submitted that the Examiner must search and examine them together, as MPEP 803.02 specifically provides that members of a *Markush* group must be searched and examined together, if they are not too many

in number. Moreover, the examination of the elected species can be extended to the non-elected species.

Therefore, it is respectfully submitted that the Election of Species Requirement should be reconsidered and withdrawn because the species set forth in the claims are sufficiently few in number such that a search and examination thereof can be made without serious burden to the Examiner, and a claim reciting all species of Group C has previously been deemed allowable.

At the very least, it is respectfully requested that the applicants be permitted to elect two species of Group C, namely species (i) CFC T-cells and T-cells, and species (ii) CFC B-cells and B-cells. It is accepted in the art that T-cells and B-cells are closely related, as both are lymphocytes and both function in antigen recognition. Further, it is USPTO practice to recite T-cells and B-cells as members of a single claim, as evidenced by US patents 5,620,689, 5,646,251 and 6,045,788.

### **CONCLUSION**

Enforcing the present Restriction and Election of Species Requirements would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, a shortened patent term may result in any divisional or continuing applications filed).

Further, Restriction has not been shown to be proper, especially since the requisite showing of serious burden has not been made. Indeed, the search and examination of each Group and species is likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner.

All of the preceding remarks, therefore, mitigate against restriction. In view of the foregoing, reconsideration and withdrawal of the restriction and election of species requirements and favorable examination of Claims of Group I and II on the merits are respectfully requested.

If any fee is determined to be due for consideration and entry of this response, the Assistant Commissioner is authorized to charge the fee or credit any overpayment to Deposit Account No. 50-0320.

Respectfully submitted,

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